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Miele

510 (K) Summary

This 510 (K) Summary information is being submitted in accordance with the requirements of SDMA 1990 and 21 CFR807.81 Subpart E- Pre-market Notification Procedures.

Product Miele G7881 Dental Thermal Disinfector

510 (K) number K031799

Legally Marketed Device Substantial equivalence of the Miele G7881 Dental Thermal Disinfector exists to the Miele G7781 Dental Thermal Disinfector (K950518). The cycle parameters for high-level disinfection have not been changed from the G7781 Dental Thermal Disinfector.

Description The G7881 Dental Thermal Disinfector is a washer/disinfector for aqueous cleaning and simultaneous thermal disinfection of dental instruments and accessories. It operates with three spray arms on three different levels. A powerful circulation pump moves 2.8 gallons of water at a rate of 105 gallons/minute. The specially designed jets on the spray arms spray the water onto the wash load at a low pressure (About 13 psi) to prevent any goods from being washed off the racks.

Functional design The complete unit is made of electro-polished stainless steel, the exterior is additionally powder coated. The unit is equipped with a microcomputer control. An integrated water softener ensures consistently high water quality; the steam condenser comes standard and minimizes contaminated aerosols and odor affecting the environment.

The powerful circulation pump circulates 2.8 gallons of water at a rate of 105 gallons/minute through spray arms with precisely directed jets. The double spray arm combines high and low pressure jets. These differences in the flow velocity rates result in a low frequency modulation, which has significant advantages for cleaning effectiveness.

Performance Characteristics

The Thermal Disinfection Process

The thermal disinfection process relies upon the two physical parameters, temperature (93°C/200°F) and time (10 minutes) minimum. These parameters are easy to control, therefore, errors are improbable. The cycle parameters for high level disinfection have not been changed from the G7781 Dental Thermal Disinfector.

Intended Use

High Level Disinfection

The G7881 Dental Thermal Disinfector is suitable for automatic treatment of dental instruments and accessories. It cleans and in the disinfection programs simultaneously disinfects at 93°C/200°F instruments and accessories. The high level disinfection showed a 6-log reduction of an appropriate myco bacterium species. Since the cycle parameters have not changed from the G7781 Dental Thermal Disinfector additional testing was not necessary.

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Instruments suitable for processing in the thermal disinfector

All instruments, accessories and other items to be cleaned and disinfected in the G7881 Dental Thermal Disinfector must be heat resistant to a temperature of up to 95°C/203°F and corrosion resistant in the presence of heat and alkalinity.

Comparison to Legally marketed Device

G7881	G7781
External size: H33.5"xW23.5"xD23.5"	External size: H33.5"xW23.5"xD23.5"
Wash chamber Size H19.5"xW21"x19.5"	Wash chamber Size H19.5"xW21"x19.5"
Circulation Pump with a turnover volume of 105 Gallons/minute	Circulation Pump with a turnover volume of 105 Gallons/minute
3 spray arms	3 spray arms
Thermal disinfection at 93°C/200°F/10 minutes	Thermal disinfection at 93°C/200°F/10 minutes
Microcomputer control for higher accuracy and safety	Microcomputer control for higher accuracy and safety
Digital display	Digital display
Disinfection control light for higher level of safety	Disinfection control light for higher level of safety
26 Fault codes displayed for easy servicing	9 Fault codes displayed for easy servicing
Optional dosing system for liquid detergents for accurate and reproducible dosage	Optional dosing system for liquid detergents for accurate and reproducible dosage
One liquid door dispenser	One liquid door dispenser
Programmable alarm when program is finished	No alarm sounds when program is finished

Non-clinical tests

Changes for G7881 are limited to the control panel. Because high level disinfection cycles parameters were not changed from K950518 it was not necessary to perform additional testing, however additional testing was done in accordance with German Health Authority guidelines Federal Health Report 1980:23:364-35-65.
All studies proved physical removal or thermal inactivation to a sufficient degree.

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Conclusions

The G 7881 Dental Thermal Disinfector does clean instruments contaminated with blood, extremely well.

The surface temperatures reach 93°C/200° for at least 10 minutes resulting in high-level disinfection. The cycle parameters from the predicate device are retained for the G7881 Dental Thermal Disinfector. The wash action combined with the thermal inactivation reduces the amount of live bacteria on the instruments by more than log-6 as demonstrated in the previous submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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Mr. Steve Polinski
Regulatory Affairs
Miele Inc.
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Princeton, New Jersey 08540

Re: K031799
Trade/Device Name: Milele G7881 Dental Thermal Disinfector
Regulation Number: 880.6992
Regulation Name: Medical Washer-Disinfector
Regulatory Class: II
Product Code: LDS
Dated: October 13, 2003
Received: October 14, 2003

Dear Mr. Polinski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

October 2003 K031799

Statement of Indication for Use

The Miele G 7881 Dental Thermal Disinfector is intended to clean and high-level disinfect heat stable reusable dental instruments and accessories using a thermal process. The cycle parameters for high-level disinfection are 93°C for 10 minutes. The Miele G7881 Dental Thermal Disinfector also has the following cleaning and high-level disinfection cycles:

Program	Program Description						
		1. Pre-wash	2. Cleaning and/or thermal disinfection	3. Interim rinse I with Neutralization	4. Interim rinse II	5. Final rinse 1) and/or disinfection	6. Drying (extra program)
Wash	Wash program without disinfection	X Cold water intake	X Cleaning 60°C/3'		X Cold water intake	X Rinse 65°C/1' (DI) DOS 2	X
Rinse (cold)	Rinse only To rinse items before a wash program, to avoid excessive foam			X Rinse Cold water			
Drain	For draining water out of the machine, e.g., when a program has been interrupted or the "Drain/Fill" indicator illuminates. (Turn the program selector to the "Stop" f position first).						
Disinfection vario	Recommended program for protein soils such as blood and tissue. For cleaning and thermal disinfection at 93□C with 10 minutes holding time for stainless steel instruments.	X Cold Water Intake	X Cleaning 55°C/5'	X DOS 3	X Cold Water intake	X Rinse and Disinfection 93°C/10'	X
Disinfection 93°C-10'	For thermal disinfection and cleaning of stainless steel instruments at 93□C with 10 minutes holding time.		X Disinfection 93°C/10'	X DOS 3		X Rinse 75°C/3' (DI) DOS 2	X

Susanna F. Barnes

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K031799

X= Sections included in a program (with temperature/temperature holding time)